Chapter 11

Experimental Use Defense to Patent Infringement

Leora Ben-Ami, Christopher Jagoe & Peter Fratangelo

§ 11:1 Introduction

The Federal Circuit continues to recognize a judicially created experimental use defense to patent infringement.[1] The defense currently exists in a form limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[2] Activity does not qualify under the defense when it is undertaken in the "guise of scientific inquiry" but has "definite, cognizable, and not insubstantial commercial purposes."[3]

There has never been a line, precisely defined, between permitted experimental uses and prohibited infringement, but examination of

1. Madey v. Duke Univ., 307 F.3d 1351, 1361 (Fed. Cir. 2002).
2. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000).
3. *Id.* (quoting Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984)).

the case law regarding the experimental use exception provides insight and gives guidance on permitted and prohibited activities.[4] Use of a patented invention for "philosophical inquiry," today called scientific inquiry (more on this later), is an experimental use exempt from infringement liability, while use of a patented invention for "definite, cognizable, and not insubstantial commercial purposes," even "in the guise of 'scientific inquiry'" is an infringing use, not an experimental use.[5] For example, the use of a patented compound or composition in clinical trials to generate data in order to gain government approval of a drug is not an experimental use under the common law experimental use exception.[6] However, such activities are now protected by the safe harbor provision of section 271(e)(1) of the Patent Act.[7] This statutory exception, though primarily applicable to the pharmaceutical and biotech industry, may explain the paucity of cases pushing for a clearer definition of the experimental use doctrine.

§ 11:2 Historical Development

The common law experimental use exception has deep historical roots and has long been understood to be necessary for the patent law to serve its constitutionally mandated purpose of promoting "Progress of Science and useful Arts."[8] Its origin is traced to an opinion by Justice Story of the Supreme Court in 1813, in which he affirmed the trial judge's instruction on patent infringement, stating, "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[9] Justice Story subsequently expanded on this concept, declaring, "the making of a patented machine to be an offence . . . must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."[10]

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4. The reader should not be confused with cases holding that an experimental use, even when done publicly in the prior art, does not create a bar to patentability under 35 U.S.C. § 102(b). *See, e.g.*, Petrolite Corp. v. Baker Hughes, Inc., 96 F.3d 1423, 1426–27 (Fed. Cir. 1996). See also *supra* section 5:2.3[B][2] for a further discussion of the experimental use exception to public use qualifying as prior art.
5. *Roche*, 733 F.2d at 863.
6. *Id.*
7. See *supra* section 8:1.8 for a further discussion of the section 271(e)(i) exception to infringement.
8. U.S. CONST. art. 1, § 8, cl. 8.
9. Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813).
10. Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813).

The experimental use exception became an accepted part of patent law, so that by 1861 the law was "well settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee."[11]

§ 11:3 Cases

Although long established, there are relatively few cases that discuss or apply the doctrine of experimental use as an exception to patent infringement. By their nature such activities cause little or no harm to the inventor of the subject matter, which explains why few cases address this issue. Most experimental uses are small-scale uses, and therefore potential damages, should the patentee prevail in challenging the exception, are likely to be small. The fact that many of these uses may meet the requirements of the experimental use exception, together with the probability of relatively small damages even if successful, probably reduces the instance of these suits and decreases the likelihood that those brought will reach trial or a dispositive decision by a court. Nonetheless, the frequent appearance of improvements on patented products and the development of patented processes by parties other than those who own the patent suggest that experimental uses are routine.[12]

§ 11:3.1 Roche Products, Inc. v. Bolar Pharmaceutical Co.

In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[13] the Federal Circuit held that a generic drug company, Bolar, was liable for infringement when it used Roche's patented drug in an effort to obtain FDA approval for the sale of a generic version of the drug following patent expiration. Bolar obtained 5 kg of the drug from a foreign manufacturer to "form into 'dosage form capsules, to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies' necessary for a New Drug Application to the United States Food and Drug Administration."[14] Bolar's use of the patented drug

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11. Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861).
12. *See, e.g.*, Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d. 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part) ("A rule that this information cannot be investigated without permission of the patentee is belied by the routine appearance of improvements on patented subject matter, as well as the rapid evolution of improvements on concepts that are patented.").
13. Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).
14. *Id.* at 860.

was for "testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent."[15] In finding that Bolar's use was not within the experimental use exception, the Federal Circuit stated that "Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[16] Giving further guidance as to the extent of the experimental use exception, the court explained, "[w]e cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[17]

§ 11:3.2 Deuterium Corp. v. United States

Following the decision on the experimental use exception in *Roche*, Judge Rader, later of the Federal Circuit, issued the decision of the court in *Deuterium Corp. v. United States*,[18] in which he addressed the applicability of the experimental use exception in a case before the U.S. Court of Claims.[19] Judge Rader described the difference between permitted and prohibited experimental uses as "distinguish[ing] experiments of a purely intellectual character from experiments designed to adapt the invention to pecuniary and business uses."[20]

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15. *Id.* at 861.
16. *Id.* at 863.
17. *Id.* Bolar also argued that if its use of the patented drug to derive FDA required test data was not exempt from infringement as an experimental use, the court should create a new exception specifically for this situation. *Roche*, 733 F.2d at 863. The court declined, suggesting that Congress was the proper body to create a new exception to infringement. *Id.* at 864–65. Shortly following the *Roche* decision, Congress enacted 35 U.S.C. § 271(e)(1), which provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

See *supra* section 8:1.8 for a discussion of section 271(e)(1).
18. Deuterium Corp. v. United States, 19 Cl. Ct. 624 (Cl. Ct. 1990).
19. The court in *Deuterium* also found that the accused process did not involve all of the required steps of the claimed process; thus there was no infringement by the government. *Id.* at 631. The court's findings regarding experimental use might be considered not essential to the disposition of the matter, and therefore dicta. Nonetheless, the court's examination of the experimental use exception is instructive in understanding the scope of protection afforded, and the kinds of activities outside the exception.
20. *Id.* at 633.

The court found that a demonstration project designed to exhibit economically feasible commercial applications "was not strictly intellectual experimentation but development of technology and processes for commercial applications," whose "objective . . . was to develop an economically feasible commercial application" of the patented invention.[21]

The plaintiff, Deuterium Corp., was the owner of a patent that covered a process for removing hydrogen sulfide from geothermal steam.[22] The defendant, the U.S. Department of Energy (DOE), contracted with Pacific Gas and Electric Company (PG&E) to jointly fund a test of defendant EIC Laboratories, Inc.'s (EIC) steam cleansing process.[23] The contract required PG&E to "design, operate, test, decommission, and evaluate a facility that removes hydrogen sulfide from 100,000 pounds of steam per hour."[24] PG&E contracted with EIC to perform this task. EIC planned a "four-month test as the centerpiece of the demonstration" during which it would "tap the main steam line, treat 100,000 pounds of steam per hour, and return the cleansed steam to the main line upstream of PG&E's turbines."[25] Due to a rupture of a pipe elbow, the test was cut short after just 120 hours.[26] Deuterium sued DOE alleging infringement of its patented process by a subpart of EIC's pilot plant.[27]

With respect to experimental use, the court first acknowledged that "an experimental use does not infringe."[28] In trying to determine the contours of the exception, the court noted that the Federal Circuit in *Roche* quoted extensively from Professor Robinson's treatise,[29] which provides in part: "[I]f the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent."[30] The court interpreted Professor Robinson's explanation as "distinguish[ing] experiments of a purely intellectual character from experiments designed to adapt the invention to pecuniary and business uses."[31] With respect to the case at bar, the court found that "DOE's participation

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21. *Id.*
22. *Id.* at 625.
23. *Id.*
24. *Id.*
25. *Id.*
26. *Id.*
27. EIC was a third-party defendant in the action. *Id.* at 624.
28. *Id.* at 631.
29. W. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890).
30. *Deuterium*, 19 Cl. Ct. at 633.
31. *Id.*

[in the accused infringing process] was not strictly intellectual experimentation, but development of technology and processes for commercial applications," and the "objective of the demonstration was to develop an economically feasible commercial application" of the patent.[32] Like the Federal Circuit did in *Roche*, the court drew a distinction between "intellectual experimentation," which is the testing of a patented invention to gain information and knowledge, and "development of technology" for commercial applications.[33] The former is permitted while the latter is prohibited.

In reaching its conclusions, the court in *Deuterium* found significant a proposal submitted by PG&E to DOE that later became part of the agreement between the parties and that described the purpose of the allegedly infringing demonstration facility: "Because of the inherent advantages of [the system used in the facility], PG&E and Union believe it is in the best interest of ERDA [Energy Research & Development Administration] and in the national interest to complete the development and commercialization of EIC's upstream H2S [hydrogen sulfide] removal system."[34] The court concluded that "the demonstration facility anticipated development and commercialization of the steam cleaning process."[35] Further distinguishing between research that meets the experimental use exception, and development of commercial products that constitutes infringement, the court found:

> The EIC pilot plant has none of the hallmarks of an experiment conducted for curiosity, amusement, or intellectual stimulation. Rather, on the continuum from one-time laboratory tests to lengthy laboratory experimentation, to small field tests, to scale demonstration projects, to large-scale pilot projects, to commercial exploitation, the EIC scale plant is just short of profitable exploitation. Indeed, for a short period, steam processed at the EIC facility helped generate commercial electricity.[36]

Thus, demonstration projects designed to develop and exhibit economically feasible commercial applications of a product or process are part of infringing development work, and not research exempted as experimental use.

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32. *Id.*
33. *Id.*
34. *Id.* at 633–34.
35. *Id.* at 634.
36. *Id.*

§ 11:3.3 Embrex, Inc. v. Service Engineering Corp.

The Federal Circuit once again was presented with the issue of experimental use in *Embrex, Inc. v. Service Engineering Corp.*[37] There the Federal Circuit found that tests conducted by scientists to determine the viability of injecting eggs without infringing the patent at issue, in combination with Service Engineering Corp.'s (SEC) development of and solicitation of orders for its infringing machine was not an experimental use.[38] The alleged infringer "performed the tests expressly for commercial purposes . . . [and its] chief commercial purpose was to demonstrate to its potential customers the usefulness of the methods performed" by its commercial product.[39]

Embrex was the exclusive licensee of a patent that claimed "methods for inoculating birds against disease by injecting vaccines into a specified region of the egg before hatching."[40] This method has the advantage of inoculating birds such as chickens while they are still in the egg, reducing the risk that chickens will succumb to infections that can infect an entire flock.[41] After settling an earlier infringement suit brought by Embrex,[42] SEC attempted to build and sell an *in ovo* injection machine.[43] SEC developed a prototype device and hired two scientists to investigate the possibility of injecting chicken embryos outside the region covered by Embrex's patent. The first scientist, Dr. Davis, suggested that perhaps the embryos could be inoculated by injecting vaccine into a region of the egg not mentioned in Embrex's patent, and he tested his method by injecting india ink into the egg.[44] He also designed a stand to hold an egg in a way that might assist in the effort to ensure the injection did not enter the part of the egg covered by Embrex's patent. The second scientist, Dr. Rosenberger, used this stand to conduct tests on the practicality of injection outside

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37. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343 (Fed. Cir. 2000).
38. *Id.* at 1349.
39. *Id.*
40. *Id.* at 1346.
41. *Id.*
42. Following failed efforts to interest Embrex into using SEC's devices for transferring eggs and allowing SEC to make Embrex's *in ovo* injection machines, SEC contacted two other companies about collaborating to design around Embrex's patent. Embrex sued SEC for patent infringement, and the parties reached a settlement that led to the dismissal of the suit. *Id.*
43. Thus, SEC apparently infringed, was sued, settled, and then infringed again trying to design a machine to compete with Embrex. While the court does not state that these facts are relevant to its decision, the court purposefully included these facts in its opinion, and the circumstances of the case should always be understood when considering the court's holding and statements. *Id.*
44. *Id.*

the patented region.[45] Dr. Rosenberger used india ink to determine if the eggs could reliably be injected into the non-patented region, and he used vaccine to determine if the embryos developed immunity.[46] The tests showed that the injected embryos received little immunity and that most injections penetrated into the region of the egg covered by Embrex's patent.[47] While these tests were being conducted, SEC "began soliciting orders for its *in ovo* injection device . . . effectively depriving Embrex of sales."[48]

In a per curiam opinion, the Federal Circuit found that the offer for sale of the device could not be the basis for infringement of Embrex's method patent, but tests performed by Drs. Davis and Rosenberger could have been the basis of the jury's finding of infringement, and these actions did not qualify as experimental uses rather than infringement.[49] The court cited *Roche* for the proposition that the alleged infringing use cannot be considered an experimental use where it has "definite, cognizable, and not insubstantial commercial purposes."[50] In this case, "SEC performed the tests expressly for commercial purposes [and] SEC's chief commercial purpose was to demonstrate to its potential customers the usefulness of the methods performed by its *in ovo* injection machines."[51] Thus, SEC's use of the patented process was not experimental use.[52] As was the case in *Roche* and *Deuterium*, a use that is part of product development and commercialization is not work done in order to gain knowledge or conduct research, and is therefore infringing.

§ 11:3.4 Madey v. Duke University

The Federal Circuit addressed the application of the experimental use exception in *Madey v. Duke University*.[53] Madey was a well-respected Stanford University physicist who had developed a free electron laser (FEL).[54] While at Stanford, Madey obtained sole ownership of two patents practiced by this FEL equipment.[55] In the mid-1980s Duke University recruited Madey, who left Stanford to come to Duke, bringing his FEL research lab with him.[56] After about a decade

45. *Id.* at 1346–47.
46. *Id.* at 1347.
47. *Id.*
48. *Id.*
49. *Id.* at 1349.
50. *Id.* (quoting *Roche*, 733 F.2d at 863).
51. *Id.*
52. *Id.*
53. Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).
54. *Id.* at 1352.
55. *Id.*
56. *Id.*

at Duke, Madey and the university had disagreements on the way Madey was running the lab, causing Madey to resign from Duke in 1998. Duke continued to operate some of the equipment in the lab after Madey departed, prompting Madey to sue Duke for patent infringement.[57] The district court applied the experimental use exception and granted summary judgment of non-infringement to Duke based on its non-profit, educational status.[58]

On appeal, addressing the experimental use exception, the Federal Circuit first dismissed an argument that the experimental use exception no longer exists, reiterating that "the experimental use defense persists albeit in the very narrow form articulated by this court" in *Embrex* and *Roche*.[59] Next, the court held that use of a patented invention does not automatically qualify as experimental use merely by the status of the institution as a research university or as a non-profit entity, without "any detailed analysis of the character, nature and effect of the use."[60] Federal Circuit "precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."[61] While Duke's use of the patented laser technology may not have been for "commercial" purposes, "these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects."[62] In other words, a university or other non-profit organization does not have blanket protection of all uses of a patented invention, regardless of the purpose and nature of the use, by the experimental use exception. "[T]he profit or non-profit status of the user is not determinative."[63] Importantly, the court did *not* hold that no use of a patented invention by a university could be an experimental use exempt from infringement, but rather that a university does not get an automatic exception to infringement by virtue of being a university. Each alleged infringing use must receive a "detailed analysis of the character, nature and effect of the use," to determine if it is research performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," or if it is done in the "guise of scientific inquiry" but has "definite, cognizable, and not insubstantial commercial purposes," just as would occur if the use of the patented invention was by a for-profit entity or an

57. *Id.*
58. *Id.* at 1356, 1362.
59. *Id.* at 1361.
60. *Id.* at 1362.
61. *Id.*
62. *Id.*
63. *Id.*

individual.[64] In the case of a university, the commercial purpose need not be sales of a product, but actions in furtherance of the university's legitimate business objectives of educating and enlightening students and faculty.[65]

The Federal Circuit remanded the case back to the district court to consider the applicability of the experimental use exception with the instruction that "[t]he correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[66] On remand the district court determined the question of experimental use was one that required a finding of fact and denied summary judgment.[67]

§ 11:4 Other Views

The experimental use exception to infringement was also recently addressed by Federal Circuit Judge Newman in an opinion concurring in part and dissenting in part in *Integra Lifesciences I, Ltd. v. Merck KGaA*.[68] The Supreme Court, in reversing the decision of the Federal Circuit in *Integra*, cited Judge Newman's opinion with approval, indicating support for her analysis and summary of experimental use.[69] *Integra* involved application of the safe-harbor for pharmaceuticals embodied in section 271(e)(1) of title 35, which was enacted by Congress shortly after the decision in *Roche*. The *Integra* majority narrowly construed section 271(e)(1) to apply only to clinical trials conducted to obtain FDA approval of a drug, and not to the accused pre-clinical research conducted for drug discovery.[70] Judge Newman dissented from the majority's result and argued that at the very least the case should be analyzed under the common law research exception.[71] The majority declined to apply the experimental use defense for the first time on appeal. Nevertheless, Judge Newman's opinion is

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64. *Id.* at 1362 (quoting *Embrex*, 216 F.3d at 1349).
65. Duke filed a petition for certiorari to the Supreme Court, arguing that in effect the Federal Circuit has extinguished the experimental use exception by its holding. The Solicitor General filed an amicus curiae brief on behalf of the U.S. government, disagreeing with Duke's interpretation of the Federal Circuit's decision and urging the Court to deny the petition. Duke's petition for certiorari was denied. 539 U.S. 958 (2003).
66. *Id.* at 1363.
67. Madey v. Duke Univ., 413 F. Supp. 2d 601 (M.D.N.C. 2006).
68. Integra Lifesciences I, Ltd. v. Merck KGaA., 331 F.3d 860, 875 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part), *rev'd*, 545 U.S. 193 (2005).
69. Merck KgaA v. Integra Lifesciences I., Ltd., 545 U.S. 193, 205 n.7 (2005).
70. *Integra*, 331 F.3d at 867–68.
71. *Id.* at 872.

informative on the law and application of the experimental use exception.[72]

Judge Newman first explains that Justice Story's use of "philosophical" was a reference to "natural philosophy," which in this context was the term for what today would be called "science"[73] and that the Federal Circuit has never attempted to "define the boundaries of the research exception for all purposes and all activities, other than to observe that there is a generally recognized distinction between 'research' and 'development,' as a matter of scale, creativity, resource allocation, and often the level of scientific/engineering skill needed for the project."[74] Thus, "[t]he subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or 'design around' it."[75] When determining whether the experimental use exception applies, Judge Newman argues that:

> [A]n ultimate goal or hope of profit from successful research should not eliminate the exception. The better rule is to recognize the exception for research conducted in order to understand or improve upon or modify the patented subject matter, whatever the ultimate goal. . . .
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> [A] patent is infringed by and bars activity associated with development and commercialization of infringing subject matter, but the research itself is not prohibited, nor is comparison of the patented subject matter with improved technology or with designs whose purpose is to avoid the patent.[76]

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72. *See Merck KgaA*, 545 U.S. at 205 n.7.
73. *Integra*, 331 F.3d at 875 n.8 (Newman, J., concurring in part, dissenting in part) ("By 'philosophical' experiments Justice Story was referring to 'natural philosophy,' the terms then used for what we today call 'science.' For example, in the volume on *Classification of Subjects of Inventions Adopted by the United States Patent Office*, January 1, 1868 (GPO 1868), the section headed 'Philosophical Instruments–Class XXV' lists 'Philosophical Apparatus, Scales, Measures, and Instruments of Precision.'").

    See also Mueller, Janice, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications For University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 929 n.44 (2004) ("Other evidence of the early use of philosophical to mean scientific includes the founding of the American Philosophical Society. Launched in Philadelphia in 1734 at the urging of Benjamin Franklin, the society pursued 'all philosophical Experiments that let Light into the Nature of Things, tend to increase the Power of Man over Matter, and multiply the Conveniences or Pleasures of Life.' Early members of the Society 'included doctors, lawyers, clergymen, and merchants interested in science, and also many learned artisans and tradesmen like Franklin.'"; internal citations omitted).
74. *Integra*, 331 F.3d at 876.
75. *Id.* at 875.
76. *Id.*

However, Judge Newman's opinion, as pointed out by Judge Rader, did not note that the judge-made doctrine is rooted in the notions of *de minimis* infringement better addressed by limited damages, citing his own opinions in *Embrex* and *Deuterium*.[77]

77. *See Embrex*, 216 F.3d at 1352–53 (Rader, J., concurring); *Deuterium*, 19 Cl. Ct. at 631 (Rader, J.) ("This court questions whether any infringing use can be *de minimis*. Damages for an extremely small infringing use may be *de minimis*, but infringement is not a question of degree.").